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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,923	03/23/2001	Sarjeet Gill	02307O093800	9534

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EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary***File Copy*

Application No.

09/815,923

Applicant(s)

GILL ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner, at (703) 306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

**Please note:** The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-5 and 11-12, drawn to a product described as an “isolated nucleic acid encoding an insect cell membrane transporter polypeptide” and “an isolated cell membrane transporter polypeptide” and a “cell comprising a recombinant nucleic acid” wherein ONE protein and ONE nucleic acid sequence encoding said protein must be selected from the following sequences: SEQ ID Nos. 1-12 and 15-16 (see Sequence Restriction below), classified in class 536, subclass 23.1; class 530, subclass 300+, 350+; class 435, subclass 252.3.
  - II. Claims 6-8, drawn to a method for “screening for a compound which modulates activity of an insect cell membrane transporter” and a “compound identified by the method of claim 6” wherein ONE protein and ONE nucleic acid sequence encoding said protein must be selected from the following sequences: SEQ ID

Nos. 1-12 and 15-16 (see Sequence Restriction below), classified variously in class 435, subclass 6, 7.1, DIG 2-8; also variously classified depending on the structure of the compound that is identified by the method of claim 6.

- III. Claim 9, drawn to a method for “screening for a compound which binds to an insect cell membrane transporter” wherein ONE protein sequence must be selected from the following sequences: SEQ ID Nos. 2, 4, 6, 8, 10, 12 and 16 (see Sequence Restriction below), classified variously in class 435, subclass 6, 7.1, DIG 2-8.
- IV. Claim 10, drawn to a product described as a “a compound identified by the method of claim 9”, classified variously in subclass 546, 548, etc. depending on the structure of the compound.

### ***Sequence Restriction***

2. Group I-III detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicant(s) must forth elect a single amino acid sequence. For an elected Group drawn to nucleic acid sequences, the Applicant(s) must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that this is a restriction requirement to a single sequence and NOT a species election requirement.

MPEP 803.04 states:

“Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally

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constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.”

It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1 (ONE) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Examination will be restricted to only the elected sequence.

3. The inventions are distinct, each from the other because of the following reasons:
4. Groups I and IV represent patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group IV is drawn to a “a compound identified by the method of claim 9”, which requires different reagents and/or materials than Group I because Group I does not require the method steps of claim 9. Therefore, art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. They can also be classified into different classes and subclasses (see paragraph 1 above).

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Consequently, Groups I and IV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

5. Groups II and III represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group III employs method steps for "screening for a compound which binds to an insect cell membrane transporter", which are not required by the method steps of Group II. Likewise, Group II employs method steps for "screening for a compound which modulates the activity of an insect cell membrane transporter", which are not required by the method steps of Groups III. Consequently, Group III will requires different reagents (reagents for screening for a compound which binds to an insect cell membrane transporter) that are not required by Group II. In addition, since Group II does not utilize the same methods steps and reagents as Group III, Group II will produce different results than Group III in situations where these method steps and reagents are required. Therefore, Groups II and III have different issues regarding patentability and enablement and represent patentably distinct subject matter.

6. Finally, Groups I-IV represent separate and distinct inventions because Groups I-IV are drawn to patentably distinct products, whereas Groups II and III are drawn to patentably distinct methods. However, if applicant were to argue that Group I was somehow related to Groups II and III as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced

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with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product(s) as claimed (i.e., Group I) can be used in materially different process of using that product (MPEP § 806.05(h)), for example, Group I can be used in the method of Group II or the patentably distinct method of Group III.

7. Likewise, if Applicant were to argue that Groups IV was somehow related to Groups III as process of making and product made. The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, (2) the product as claimed can be made by another and materially different process e.g., cell transporters could be incubated with the compounds in solution instead of on a solid support.

8. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

9. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

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10. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic. Applicant must elect *one* single species from *each* of the subgroups below.

Subgroup 1: Species of cell transporter (see claim 1)

Applicant must elect, for the purposes of search, a single species of cell transporter e.g., Manduca sexta transporter (see specification, Examples, paragraph 176). Applicant should not elect a "broad category" of cell transporters like "proline transporter" or "acetylcholine transporter" because more than one species of cell transporter would be erroneously elected. However, applicants must indicate which "broad category" their single species election falls within i.e., Manduca sexta transporter falls within serotonin transporter category.

Subgroup 2: Species of cell (see claim 11)

Applicant must elect, for the purposes of search, a single species of cell e.g., CV-1 cells (see specification, Examples). Applicant should not elect a "broad category" of cells like "insect" or "mammalian" because more than one species of cell would be erroneously elected. However, applicant should indicate which "broad category" their single species election falls within.

11. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Applicant must elect *one* single species from *each* subgroups below. Claim 6 is generic.

Subgroup 1: Species of "test compound" (see claim 6)

Applicant must elect, for the purposes of search, a single species of test compound e.g., L-DABA (see specification, paragraph 140) wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the test compound. Applicant should not use notations like X or R when identifying the elected



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structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

Subgroup 2: Species of cell (see claim 11)

Applicant must elect, for the purposes of search, a single species of cell e.g., CV-1 cells (see specification, Examples, paragraph 176). Applicant should not elect a "broad category" of cells like "insect" or "mammalian" because more than one species of cell would be erroneously elected.

Subgroup 3: Species of cell membrane transporter (see claim 6)

Applicant must elect, for the purposes of search, a single species of cell membrane transporter e.g., Manduca sexta transporter (see specification, Examples, paragraph 176). Applicant should not elect a "broad category" of cell transporters like "proline transporter" or "acetylcholine transporter" because more than one species of cell transporter would be erroneously elected. However, applicants must indicate which "broad category" their single species election falls within i.e., Manduca sexta transporter falls within serotonin transporter category.

Subgroup 4: Species of "compound identified by the method of claim 6" (see claim 8)

Applicant must elect, for the purposes of search, a single species of compound identified by the method of claim 6 wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the compound. Applicant should not use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

12. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Applicant must elect *one* single species from *each* subgroups below. Claim 9 is generic.

Subgroup 1: Species of "test compound" (see claim 9)

Applicant must elect, for the purposes of search, a single species of test compound e.g., L-DABA or a "representative" member of the library of test compounds (see specification, paragraph 140) wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the test compound. Applicant should not use notations like X or R when identifying the elected structure

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because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

Subgroup 2: Species of solid surface (see claim 9)

Applicant must elect, for the purposes of search, a single species of solid surface e.g., microtiter plate.

Subgroup 3: Species of cell membrane transporter (see claim 9)

Applicant must elect, for the purposes of search, a single species of cell membrane transporter e.g., Manduca sexta transporter (see specification, Examples, paragraph 176). Applicant should not elect a "broad category" of cell transporters like "proline transporter" or "acetylcholine transporter" because more than one species of cell transporter would be erroneously elected. However, applicants must indicate which "broad category" their single species election falls within i.e., Manduca sexta transporter falls within serotonin transporter category.

13. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct species. Applicant must elect *one* single species from *each* subgroups below. Claim 10 is generic.

Subgroup 1: Species of "compound" (see claim 10)

Applicant must elect, for the purposes of search, a single species of compound wherein a specific structure is set forth, which clearly shows all of the atoms and bonds that are necessary to define the test compound. Applicant should not use notations like X or R when identifying the elected structure because these letters represent groups with variable members and, as a result, more than one species would be erroneously elected.

14. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have

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different issues regarding patentability and represent patentably distinct subject matter.

Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

15. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

18. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

19. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

20. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

21. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an “action on the merits” for purposes of the second action final program, see MPEP 809.02(a).

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.  
February 9, 2003

BENNETT CELSA  
PRIMARY EXAMINER  
  
